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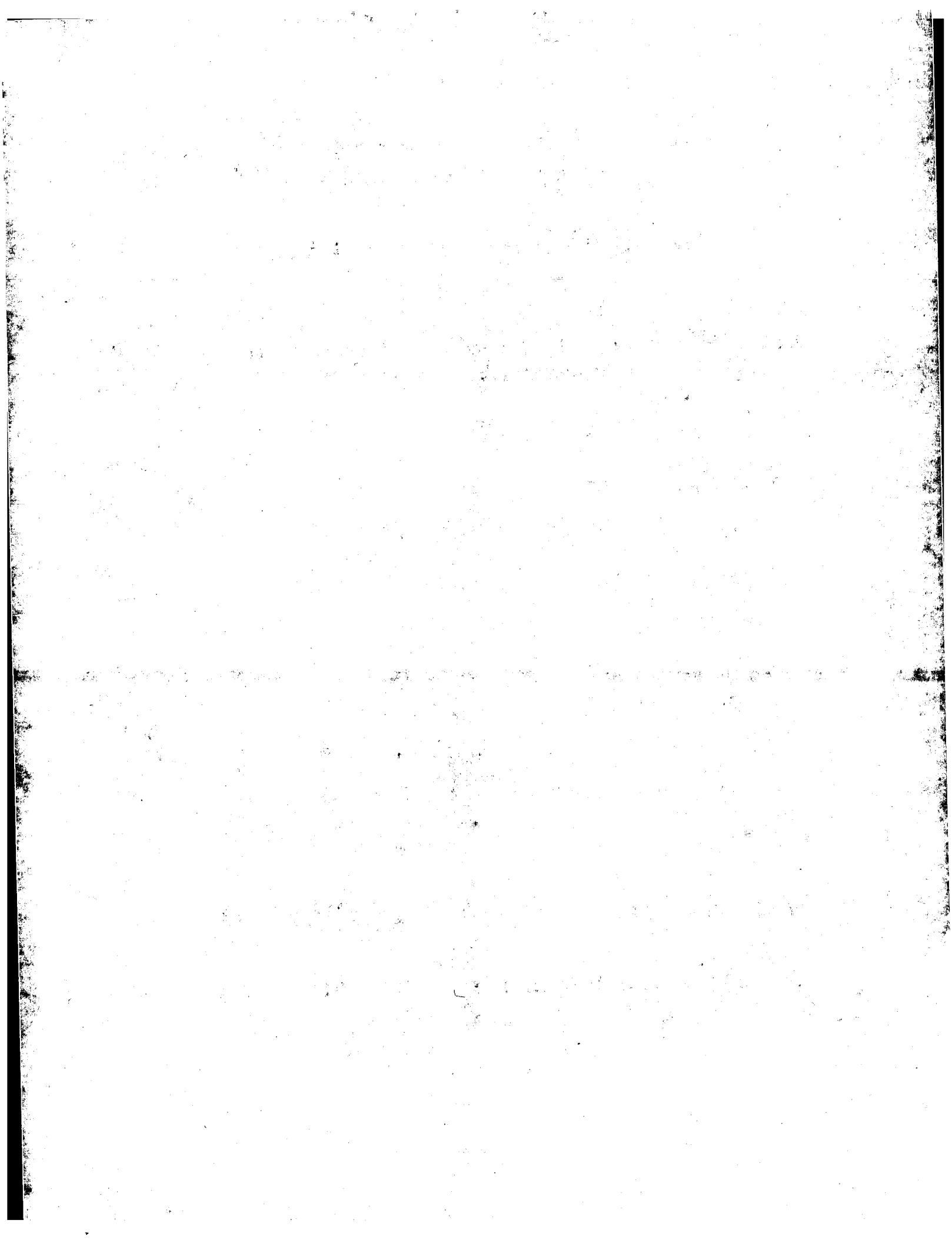
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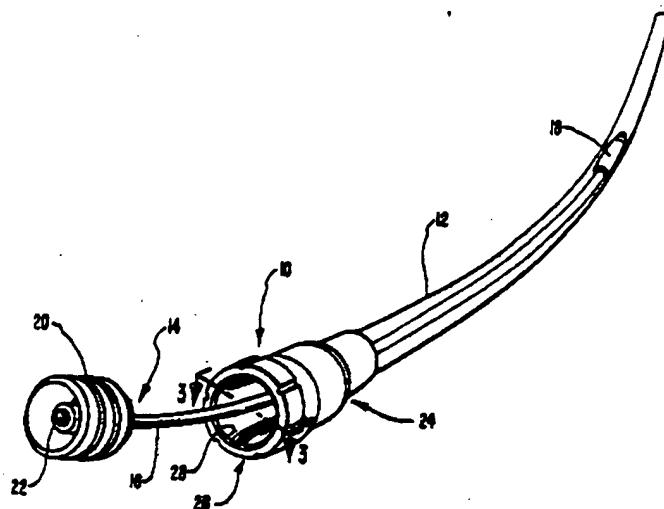
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(21) International Application Number: PCT/US91/09699 (22) International Filing Date: 23 December 1991 (23.12.91) (30) Priority data: 633,975 26 December 1990 (26.12.90) US (71) Applicant: CARDIOPULMONICS, INC. [US/US]; 5060 West Amelia Earhart Drive, Salt Lake City, UT 84116 (US). (72) Inventors: BERRY, Gaylord, L. ; 3020 East 3135 South, Salt Lake City, UT 84109 (US). KERBY, Lynn ; 1623 Casper Road, Draper, UT 84020 (US). (74) Agents: NYDEGGER, Rick, D. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).	(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent).	

Published

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With amended claims.*

(54) Title: ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE



(57) Abstract

A catheter valve (10) which can be used to effect selective closure of a catheter lumen in order to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body. The apparatus has a valve body with a hub (24) which is joined to the catheter, and a rotatable cap (26) which is joined to the hub (24). An elastomeric sleeve (38) is positioned in an opening (28) through the interior of the valve body. One end of the elastomeric sleeve (38) is joined to the rotatable cap (26) while the other end of the elastomeric sleeve (38) is joined to the hub (24). When the cap (26) is rotated in one direction to a first position, the circular opening (28) of the sleeve (38) is fully opened. When the cap (26) is rotated in the opposite direction to a second position, the elastomeric sleeve (38) is twisted intermediate the two ends so as to ultimately effect closure of the circular opening (28).

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1 ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE

BACKGROUND1. Field of the Invention

5 The present invention relates to an apparatus for a catheter valve which can be used to limit or prevent the loss of body fluid from a patient's body when the catheter is introduced into the patient's body, or which can be used to otherwise control the injection or removal of fluids through the catheter.

10

2. Technological Background

15 There are many types of medical devices which must be inserted into a patient's body, such as tubes, catheters, needles, introducer sheathes and the like. As used herein, the term "catheter" is intended to embrace within its scope any devices through which fluids are intended to be injected into a patient's body or through which there is the potential for removal or loss of body fluid from the patient's body, including by way of example but not limitation, tubes, catheters, needles, or introducer sheathes through which catheters, needles or other medical devices can be introduced into a patient's body.

20

25 When using such catheter-type devices, it is typically necessary or desireable to either control the injection of fluids into the patient's body or to control, limit or prevent fluids from escaping through the lumen of the catheter-type device. To this end, there are many types of clamping or valving apparatus which have been devised. For example, there clamps or hemostats which can be placed on the outside and used to open or close tubes or catheters by pinching or collapsing the walls, thereby controlling fluid flow through the tube or catheter either into or out of the patient's body. These types of exterior clamps or hemostats are typically intended to maintain such tubes or

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1 catheters either fully open or fully closed. However,
2 there are some circumstances in which it would be
3 desireable to effect only partial closure of the lumen of
4 the tube or catheter to permit reduced fluid flow. There
5 are other types of circumstances where constriction of the
6 lumen of such a tube or catheter must be effected in a
7 manner so as to prevent loss of blood or other body fluid
8 as another medical device is introduced through the tube or
9 catheter into the patient's body.

10 It would be highly advantageous to have a valve which
11 is capable of being used for any or all such types of fluid
12 control through a catheter-type device.

BRIEF SUMMARY OF THE INVENTION

15 The present invention is directed to a novel apparatus
16 for a catheter valve which can be used to effect selective
17 closure of a catheter lumen in order to control fluid flow
18 through the catheter lumen once the catheter is inserted
19 into a patient's body. In a preferred embodiment of the
20 invention, the valve body has a hub which is joined to a
21 catheter-type device and a rotatable cap which is joined to
22 the hub. An elastomeric sleeve is positioned in an opening
23 through the interior of the valve body and one end of the
24 elastomeric sleeve is joined to the rotatable cap while the
25 other end of the elastomeric sleeve is joined to the hub.
26 When the cap is rotated in one direction to a first
27 position, the circular opening of the sleeve is fully
28 opened. When the cap is rotated in the opposite direction
29 to a second position, the elastomeric sleeve is twisted
30 intermediate the two ends so as to ultimately effect
31 closure of the circular opening of the sleeve when the cap
32 is rotated to the second position. Due to the elastomeric
33 properties of the sleeve, the circular opening of the
34 elastomeric sleeve tends to be uniformly constricted as the
35 cap is rotated to effect closure. The catheter valve of

1 the present invention can be operated to effect full
opening or full closure of the circular opening through the
valve body and can also be operated to effect variable
constriction of the circular opening or to engage the
2 circumference of a tube or other medical device inserted
through the circular opening so as to prevent fluid flow
from passage around the circumference of the medical
device.

3 Various advantages of the invention will be apparent
10 from the drawings, description and claims which follow, or
may be learned by the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The invention will be described with additional detail
and specificity through the use of the accompanying
drawings which are briefly summarized below. The drawings
and accompanying detailed description depict the presently
preferred embodiment and presently understood best mode of
practicing the invention but are not otherwise to be
20 considered as limiting of the invention's scope, which is
set forth in the claims and which are intended to embrace
within their scope equivalent instrumentalities or
combinations.

25 In the drawings, Figure 1 is a perspective illustration
showing the valve of the present invention as used with a
catheter-type device, as for example an introducer sheath,
with an obturator that is inserted into the introducer
sheath. In Figure 1 the catheter valve of the present
invention is shown with the valve in a fully open position.

30 Figure 2 is a perspective illustration showing the
catheter valve of the present invention rotated to effect
closure of the circular opening through the valve body so
as to prevent fluid from flowing through the valve body
around the obturator.

Figure 3 is an enlarged cross-sectional view taken along line 3-3 of Figure 1.

Figure 4 is an enlarged cross-sectional view taken along line 4-4 of Figure 2.

Figure 5 is a cross-sectional view similar to that of Figure 4, but showing a smaller diameter obturator, catheter or tube and particularly illustrating the manner in which the circular opening of the catheter valve is uniformly and variably constricted to effect closure about the circumference of the device.

Figure 6A is an elevated side view of the catheter valve of the present invention which illustrates the rotatable valve cap at a first position wherein the circular opening of the valve body is fully open as illustrated in the corresponding elevated end view of Figure 6B.

Figures 6C and 6D are elevated side and end views, respectively, which particularly illustrate the rotatable valve cap rotated to an intermediate position so as to effect partial closure of the circular opening.

Figures 6E and 6F are elevated side and end views, respectively, which particularly illustrate the rotatable valve cap rotated to a second position to effect full closure of the circular opening through the valve body.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to the drawings wherein like parts are designated with like numerals throughout.

Referring first to Figure 1, the catheter valve of the present invention is generally designated at 10. For purposes of illustration only, the valve 10 is illustrated as being coupled at one end of an introducer sheath 12. In the case of the particular introducer sheath 12 which is illustrated in Figure 1, the sheath 12 is designed particularly for insertion into the right jugular vein of

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1 a patient in order to provide access to the patient's vena
cava for purposes of introducing an in vivo blood
oxygenation device. Also illustrated in connection with
the introducer sheath 12 is an obturator which is generally
5 designated at 14 and which comprises a rod-like elongated
member 16 with a tip 18 connected thereto at one end (the
distal end) and a gripping means 20 connected thereto at
the other end (the proximal end). The obturator 14 adds
10 stability to the sheath 10 and provides a blunt,atraumatic
tip 18 to facilitate the insertion of the sheath 12 into a
patient's venous system. Obturator 14 is also typically
provided with a small diameter bore 22 that runs through
the length of the elongated member 16 and through which a
15 guide wire (not shown) may be threaded and which can be
later used to aid in guiding the entry and positioning of
a medical device such as an in vivo blood oxygenation
device.

It should be understood that the sheath 12 and
obturator 14 have been illustrated merely to show a typical
20 application for which the valve of the present invention
can be advantageously utilized, but is not otherwis
intended to be limiting of the scope of the invention. Th
valve 10 may be advantageously used with any one of a
variety of different types of tubes for administration of
25 parenteral fluids, catheters for insertion into the
arterial, venous or other parts of a patient's body or
could be used in connection with various types of needles
or other introducer sheath apparatus. Thus, as noted
above, the valve of the present invention is intended to be
30 used in connection with any such catheter-type device
through which it is necessary or desireable to control,
limit or prevent infusion or withdrawal of any type of
fluids into or out of a patient.

With further reference to Figure 1, in the presently
35 preferred embodiment of the invention as illustrat d in the

1 drawings, the valve comprises a means for defining a valve
2 body with an opening ther through which communicates with
3 the interior lumen of the sheath or catheter-type device to
4 which it is connected. In the preferred embodiment, the
5 means for defining the valve body is comprised of a hub
means generally designated at 24 for joining the valve body
6 to the elongated sheath 12 and is also comprised of a cap
means as generally designated at 26 for rotatably joining
7 said hub means. A circular opening 28 is provided through
8 the interior of the valve body so as to provide fluid flow
9 through the interior of the valve body. The circular
10 opening 28 is shown in greater detail in Figure 3.

With further reference to Figure 3, in the presently
15 preferred embodiment of the invention as illustrated, the
hub means 24 is comprised of an outer cylindrical sleeve
16 clamp 32. clamp 30 and an inner cylindrical sleeve clamp 34.
Similarly, the rotatable cap means 26 is also comprised of
17 an outer cylindrical sleeve clamp 34 and an inner
cylindrical sleeve clamp 36. In a further aspect of the
18 invention, the valve is comprised of a means for
constricting the circular opening 28 through the valve body
19 as the cap means 26 is rotated relative to the hub means 24
such that when the cap means 26 is rotated to a first
20 position the means for constricting does not obstruct the
circular opening 28, and when the cap means 26 is rotated
21 in an opposite direction to a second position, the means
22 for constricting effects closure of the circular opening
23 28.

In the presently preferred embodiment, as shown best in
30 Figures 2-4 taken together, the means for constricting the
circular opening of the valve body is comprised of an
31 elongated, cylindrical elastomeric sleeve 38. Sleeve 38
has one end 42 which is clamped and held firmly between the
32 outer and inner cylindrical sleeve clamps 34 and 36 of the
33 rotatabl cap means 26, whereas the other end 44 of the
34

1 elastomeric sleeve 38 is firmly clamped and held between
the outer and inner cylindrical sleeve clamps 30 and 32 of
the hub means 24. Accordingly, when the cap means 26,
including the outer and inner cylindrical sleeve clamps 34
5 and 36 are rotated while the outer and inner cylindrical
sleeve clamps 30 and 32 of the hub means 24 are held
stationary, the elastomeric sleeve 38 is twisted
intermediate the two ends 42 and 44 of sleeve 38 so as to
effect closure of the opening 28 which is otherwise
10 provided through the sleeve 38. Thus, as shown best in
Figures 2 and 4, the elastomeric sleeve 38 will be
collapsed upon the elongated member 16 of the obturator to
provide a fluid-tight seal thereby preventing any fluid
from flowing through the opening 28 in the space around the
15 elongated member 16 of the obturator. In the alternative,
if an obturator or other tube or catheter-type device is
not inserted through the circular opening 28 of the valve
body, the elastomeric sleeve 38 can be completely collapsed
to effect full closure as illustrated, for example, in the
20 elevated end view of Figure 6F.

With continued reference to the cross-sectional views
of Figures 3 and 4, the outer cylindrical sleeve clamp 34
of the rotatable cap means 26 is provided with a square
shoulder 46. The vertical edge of the square shoulder 46
25 provides a supporting abutment for a circular rim 48 that
is formed on the inner cylindrical sleeve clamp 36. A
portion 50 of the inner cylindrical sleeve clamp 36 extends
beneath the horizontal edge of the square shoulder 46 of
outer cylindrical sleeve clamp 34. The end 42 of
30 elastomeric sleeve is firmly clamped and held between the
horizontal edge of shoulder 46 and the portion 50 of inner
cylindrical sleeve clamp 36 that extends therebeneath.

The opposite end 44 of the elastomeric sleeve 38 is
firmly held and clamped between a horizontal extension 52
35 of the outer cylindrical sleeve clamp 30 and a low r

horizontal extension 54 of the inner cylindrical sleeve clamp 32 of the hub means 24. The inner cylindrical sleeve clamp 32 of the hub means 24 is also comprised of a square shoulder 56 and the vertical edge of the square shoulder 56 provides a supporting abutment for the end of the horizontal extension member 52. The inner cylindrical sleeve clamp 32 also provides an upper horizontal extension member 58 which projects beneath an overhanging lip 60 on the outer cylindrical sleeve clamp 34 of the rotatable cap means 26. Further, the inner cylindrical sleeve clamp 36 of the rotatable cap means 26 also has a horizontal support member 62 which provides a rotational bearing surface upon which the upper horizontal extension member 58 rests. The outer and inner cylindrical sleeve clamps 34 and 36 of the rotatable cap means 26 are firmly bonded or otherwise secured together so as to provide a unitary piece which rotates relative to the inner and outer cylindrical sleeve clamps 30 and 32 of the hub means 24.

Because of the rotatable bearing surface provided by the horizontal support member 62 which supports the horizontal extension member 58, the outer cylindrical sleeve clamp 34 can be grasped and rotated in either direction therefore rotating both the inner and outer cylindrical sleeve clamps 34 and 36 relative to the outer and inner sleeve clamps 30 and 32 of the hub means 24. The effect of this rotational movement will be to twist the elastomeric sleeve 38 such as illustrated at point 40 thereby collapsing the elastomeric sleeve 38 at that point. In this manner, the elastomeric sleeve 38 will serve as a means for constricting the circular opening in an essentially uniform, variable fashion, as illustrated best in the elevated end views of Figures 6B, 6D and 6F.

In Figure 6B the elastomeric sleeve is not rotated so that the circular opening 28 is fully open. In Figure 6D the rotatable cap means has been partially rotated to

- 1 effect partial closure of the circular opening 28 by causing a partial collapse of the elastomeric sleeve 38 at point 40 due to the twisting effect of rotating one end of the sleeve 38 relative to the other. In Figure 6F full
- 5 closure of the circular opening has been effected by completely rotating one end of the elastomeric sleeve 38 relative to the other until the elastomeric sleeve has been completely twisted to a closed condition.

As will be further appreciated in reference to Figures 10 2-5, the elastomeric sleeve 38 can also provide effective closure and fluid-tight seal against an obturator or other tube-like device which is inserted through the circular opening 28. In the case of Figures 2-4, the elongated rod-like member 16 of the obturator can be left free to slide 15 in or out of the circular opening when the elastomeric sleeve 38 is in an open or partially closed condition, or alternatively the elastomeric sleeve 38 can be twisted to effect closure and to provide a fluid-tight seal against the elongated rod-like member 16 by the aforementioned 20 rotational movement of the cap means 26 relative to the hub means 24. Figure 5 illustrates how a tube or rod of smaller diameter such as illustrated at 16A can also be effectively sealed within the circular opening 28 by twisting one end of the elastomeric sleeve 38 relative to 25 the other.

With further reference to Figures 3 and 4, the outer cylindrical sleeve clamp 30 is tapered at portion 64 and terminates in a cylindrical inner collar 66. A cylindrical outer collar 68 fits over the inner collar 66 and is used 30 to clamp the end of the sheath or other catheter-like device 12 between the two so as to join the hub means 24 to the sheath or catheter-like device 12.

The manner of operating the valve of the present invention is best understood in reference to Figures 6A-6F. 35 As will be seen best in the levated side views of Figures

6A, 6C and 6E, the outer cylindrical sleeve clamp 34 also serves as a cap which can be rotated relative to the hub of the valve. The rotatable cap has a lip 60 which extends partially around the circumference of the valve. At one end of the lip 60 there is a notch 72 provided which defines a first position for the rotatable cap. At the other end of the lip 60, as shown best in Figure 6E, there is a second notch 76 which is formed, which defines a second position of the rotatable cap. A post 70 (see also Figures 3 and 4) is anchored in the inner cylindrical sleeve clamp 32 of the hub means.

Post 70 in conjunction with the lip 60 serves as a stop means for limiting rotational movement of the rotatable cap in either direction of rotation. Accordingly, when the rotatable cap is rotated to the position shown in Figure 6A, the elastomeric sleeve 38 is fully open so as not to obstruct the circular opening 28 of the valve body. When the rotatable cap is partially rotated as shown in Figure 6C the elastomeric sleeve 38 will partially constrict as it begins to twist at the intermediate portion of its length. Thus, as shown in Figure 6D the circular opening 28 will be partially obstructed when the cap is rotated to the position of Figure 6C. When the rotatable cap is fully rotated in the opposite direction to the notch 76 so that the rotatable cap will be held in that position by the post 70, the elastomeric sleeve 38 will effect full closure of the circular opening 28, as shown in Figure 6F. As will be further appreciated from Figures 6A, 6C and 6E taken together, the rotatable cap has a portion of its length shortened as illustrated at 74 so as to permit rotation of the cap relative to the post 70 which provides a stop for engaging the notched positions 72 or 76.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be

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1 considered in all respects only as illustrative and not
restrictive. The scope of the invention is, therefore,
indicated by the appended claims rather than by the
foregoing description. All changes which come within the
2 meaning and range of equivalency of the claims are to be
embraced within their scope.

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CLAIMS:

1. A valve for effecting selective closure of a catheter lumen to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body, the valve comprising:

means for defining a valve body with an opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and

means for constricting said opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for constricting does not obstruct said opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said opening.

2. A valve as defined in claim 1 wherein said hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

3. A valve as defined in claim 2 wherein said cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

1 second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5 5. A valve as defined in claim 2 wherein said hub means further comprises a cylindrical catheter clamp.

10 6. A reflux valve as defined in claims 1 and 2 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

15 7. A reflux valve as defined in claim 6 wherein said stop means comprises:

20 a post anchored in the inner cylindrical sleeve clamp of said hub means; and
a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

8. A valve for controlling fluid flow through a catheter connected to said valve when the catheter is inserted into a blood vessel, said valve comprising:

25 a valve body comprised of a hub means for joining said valve to said catheter and a cap means for rotatably joining to said hub means, said hub means and said cap means each comprising a means for clamping an end of an elastomeric sleeve; and

30 35 a cylindrical, elastomeric sleeve having one end clamped to said hub means, and having another end clamped to said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to

1 said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5 9. A valve as defined in claim 8 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

10 10. A valve as defined in claim 9 wherein said stop means comprises:

15 a post anchored in the inner cylindrical sleeve clamp of said hub means; and a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

11. A valve as defined in claim 10 wherein said hub means further comprises a cylindrical catheter clamp.

20 12. A valve as defined in claim 8 wherein each said means for clamping an end of said elastomeric sleeve comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25 13. A valve for effecting selective closure of a catheter lumen to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body, the valve comprising:

30 means for defining a valve body with an opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to

1 said cath ter, and cap means for rotatably joining to said hub means;

5 means for constricting said opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for constricting does not obstruct said opening, and when said valve body is rotated to a second position, said means for constricting effects closure of said opening; and

10 stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when the cap means is rotated in one direction, and so as to stop said cap means at said second position when the cap means is rotated in an opposite direction.

15 14. A valve as defined in claim 13 wherein said hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

20 15. A valve as defined in claim 14 wherein said cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25 16. A valve as defined in claim 15 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

17. A valve as defined in claim 16 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and
a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

19. A valve for effecting selective closure of a catheter lumen to prevent escape of body fluid through the catheter lumen when a tube is inserted through the catheter lumen and the catheter is inserted into a patient's body, the valve comprising:

means for defining a valve body with a circular opening therethrough which communicates with said catheter lumen, said tube extending through the circular opening into the lumen of said catheter, and said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and
means for variably constricting said circular opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for variably constricting said circular opening does not obstruct said circular opening so that said tube is freely slidable through said circular opening and the lumen of said catheter, and such that when said valve body is rotated to a second position said means for variably constricting said circular opening uniformly clamps said tube and frictionally engages said

1 tube to prevent escape of body fluid through said lumen
and around said tub through the circular opening.

20. A valve as defined in claim 19 further comprising
5 stop means for limiting rotation of said cap means relative
to said hub means so as to stop said cap means at said
first position when rotated in one direction, and so as to
stop said cap means at said second position when rotated in
an opposite direction.

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21. A valve as defined in claim 20 wherein said stop
means comprises:

 a post anchored in the inner cylindrical sleeve
 clamp of said hub means; and

15 a lip extending around a portion of the
 circumference of said outer cylindrical sleeve clamp of
 said cap means.

22. A valve as defined in claim 19 wherein said hub
20 means comprises an outer cylindrical sleeve clamp and an
 inner cylindrical sleeve clamp.

23. A valve as defined in claim 22 wherein said cap
means comprises an outer cylindrical sleeve clamp and an
25 inner cylindrical sleeve clamp.

24. A valve as defined in claim 23 wherein said means
for constricting said opening comprises a cylindrical,
30 elastomeric sleeve having one end clamped between the inner
 and outer sleeve clamps of said hub means, and having
 another end clamped between the inner and outer sleeve
 clamps of said cap means, such that when said cap means is
 rotated relative to said hub means to a first position,
 said elastomeric sleeve is untwisted and open, and when
 said cap means is rotated relative to said hub means to a
35 second position, said elastomeric sleeve is twisted and
 constricts the opening.

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1 second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

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AMENDED CLAIMS

[received by the International Bureau on 1 June 1992 (01.06.92);
original claims 1-24 replaced by amended claims 1-24
(8 pages)]

1 1. A valve for effecting selective closure of a catheter lumen to control fluid flow through said catheter lumen once a catheter is inserted into a patient's body, said valve comprising:

5 means for defining a valve body with an inside opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means, and the hub means and cap means each comprising a clamping means; and

10 means for constricting said inside opening of said valve body as said cap means is rotated relative to said hub means and said means for constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means, so as to provide an unobstructed lining along said inside opening of said valve body, such that when said cap means is rotated to a first position said means for constricting does not obstruct said inside opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said inside opening of said valve body.

15 2. A valve as defined in claim 1 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

20 3. A valve as defined in claim 2 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

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4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

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5. A valve as defined in claim 2 wherein said hub means further comprises a cylindrical catheter clamp.

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6. A reflux valve as defined in claims 1 or 2 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

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7. A reflux valve as defined in claim 6 wherein said stop means comprises:

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a post anchored in the inner cylindrical sleeve clamp of said hub means; and
a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

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8. A valve for controlling fluid flow through a catheter connected to said valve when said catheter is inserted into a blood vessel, said valve comprising:
a valve body having an inside opening, said valve body comprised of a hub means for joining said valve

1 to said catheter and a cap means for rotatably joining
5 to said hub means, said hub means and said cap means
each comprising a means for clamping an end of a
cylindrical elastomeric sleeve, said cylindrical,
elastomeric sleeve having one end wrapped around one
10 of said clamping means and clamped to said hub means,
and having another end wrapped around the other said
clamping means clamped to said cap means, such that
when said cap means is rotated relative to said hub
means to a first position, said cylindrical
15 elastomeric sleeve is untwisted and open, and provides
an uninterrupted seamless lining along said inside
opening of said valve body, and when said cap means is
rotated relative to said hub means to a second
position, said cylindrical elastomeric sleeve is
twisted to effect closure of said opening of said
valve body.

20 9. A valve as defined in claim 8 further comprising
stop means for limiting rotation of said cap means relative
to said hub means so as to stop said cap means at said
first position when rotated in one direction, and so as to
stop said cap means at said second position when rotated in
25 an opposite direction.

10. A valve as defined in claim 9 wherein said stop
means comprises:

30 a post anchored in the inner cylindrical sleeve
clamp of said hub means; and
a lip extending around a portion of the
circumference of said outer cylindrical sleeve clamp
of said cap means.

35 11. A valve as defined in claim 10 wherein said hub
means further comprises a cylindrical catheter clamp.

1 12. A valve as defined in claim 8 wherein each said
means for clamping an end of said elastomeric sleeve
comprises an outer cylindrical sleeve clamp and an inner
cylindrical sleeve clamp.

5 13. A valve for effecting selective closure of a
catheter lumen to control fluid flow through said catheter
lumen once a catheter has been inserted into a patient's
body, said valve comprising:

10 means for defining a valve body with an inside
opening therethrough which communicates with said
catheter lumen, said means for defining said valve
body comprises hub means for joining said valve body
to said catheter lumen, and cap means for rotatably
15 joining to said hub means said catheter lumen, and the
hub means and cap means each comprising a clamping
means;

20 means for constricting said opening of said valve
body as said cap means is rotated relative to said hub
means, such that when said cap means is rotated to a
first position said means for constricting does not
obstruct said opening and said means for constricting
having one end wrapped around and clamped by the
clamping means of the hub means, and having another
25 end wrapped around and clamped by the clamping means
of the cap means, so as to provide an unobstructed
lining along said inside opening of said valve body,
and when said valve body is rotated to a second
position, said means for constricting effects closure
30 of said opening of said valve body; and

35 stop means for limiting rotation of said cap
means relative to said hub means so as to stop said
cap means at said first position when said cap means
is rotated in one direction, and so as to stop said

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cap means at said second position when said cap means is rotated in an opposite direction.

5

14. A valve as defined in claim 13 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

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15. A valve as defined in claim 14 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

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16. A valve as defined in claim 15 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

30

17. A valve as defined in claim 16 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

35

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

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19. A valve for effecting selective closure of a catheter lumen and about a tube inserted therethrough to prevent escape of body fluid through said catheter lumen when said catheter is inserted into a patient's body, said valve comprising:

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means for defining a valve body with a circular opening through the inside of said valve body and which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter lumen, and cap means for rotatably joining to said hub means, and the hub means and cap means each comprising a clamping means; and

10

means for variably constricting said circular opening of said valve body as said cap means is rotated relative to said hub means, said means for variably constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means so as to provide an unobstructed lining along said opening along the inside of said valve body, such that when said cap means is rotated to a first position said means for variably constricting said circular opening seamlessly lines the inside of said valve body but does not obstruct said circular opening so that said tube is freely slidable through said circular opening and the lumen of said catheter, and such that when said valve body is rotated to a second position said means for variably constricting said circular opening uniformly closes around said tube and frictionally engages said tube to prevent escape of body fluid through said catheter lumen and around said tube through said circular opening of said valve body.

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20. A valve as defined in claim 19 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

5

21. A valve as defined in claim 20 wherein said stop means comprises:

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a post anchored in the inner cylindrical sleeve clamp of said hub means; and

15

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

20

22. A valve as defined in claim 19 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25

23. A valve as defined in claim 22 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

30

24. A valve as defined in claim 23 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

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1 second position, said elastomeric sleeve is twisted to
effect closure of the sleeve.

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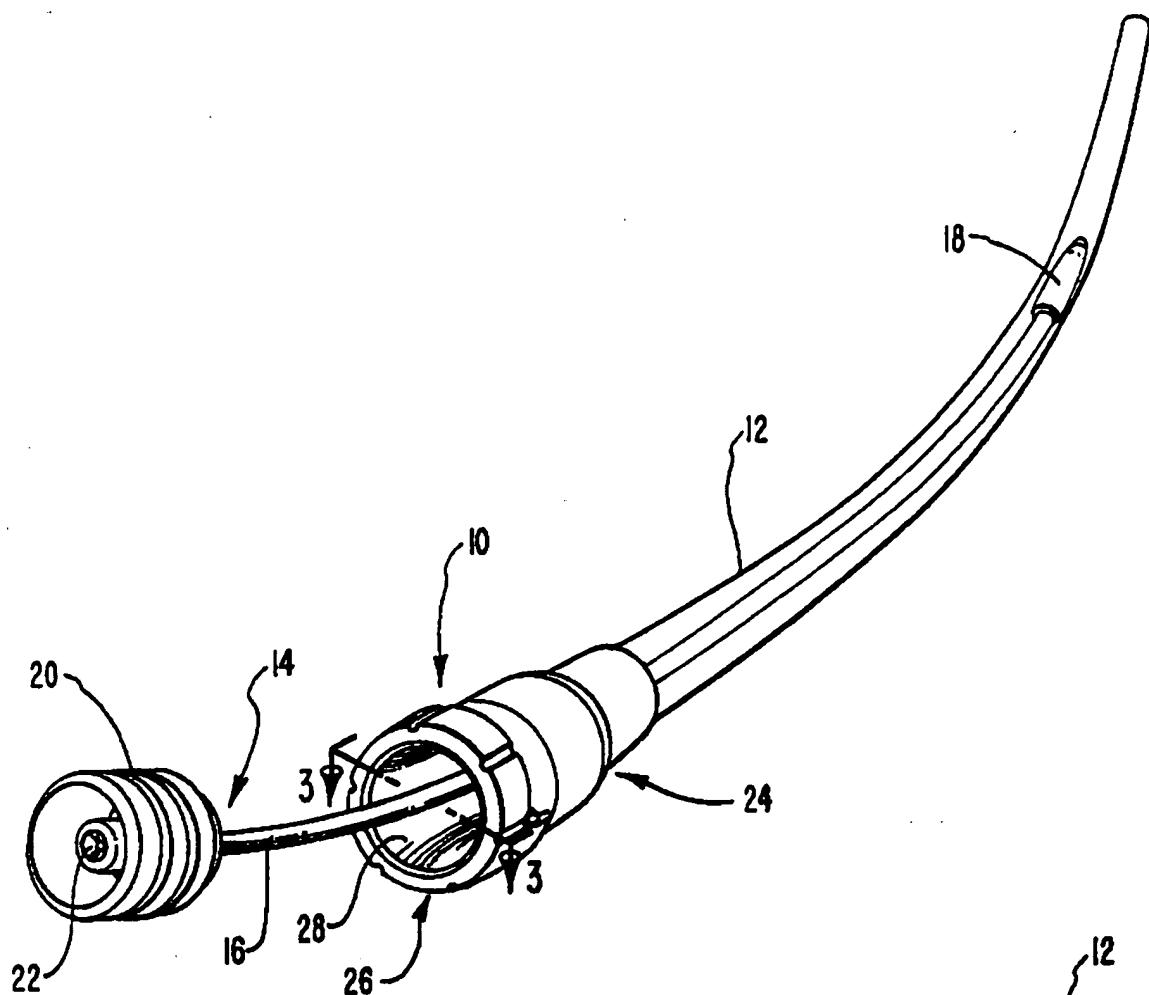


FIG. 1

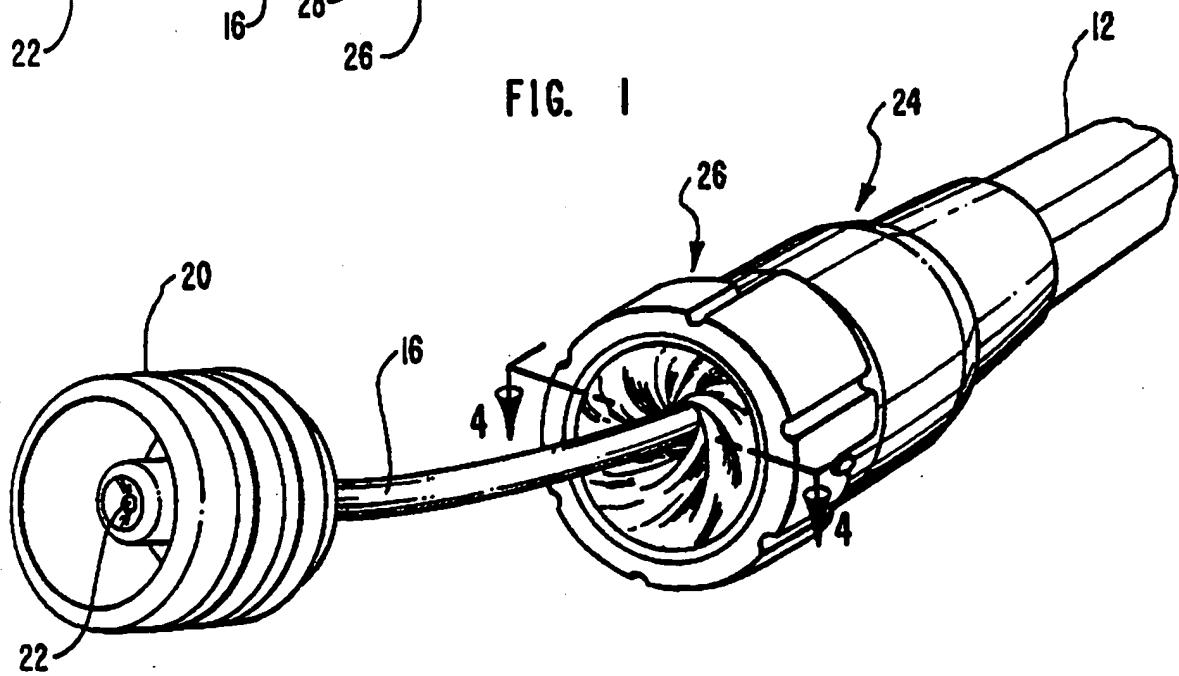
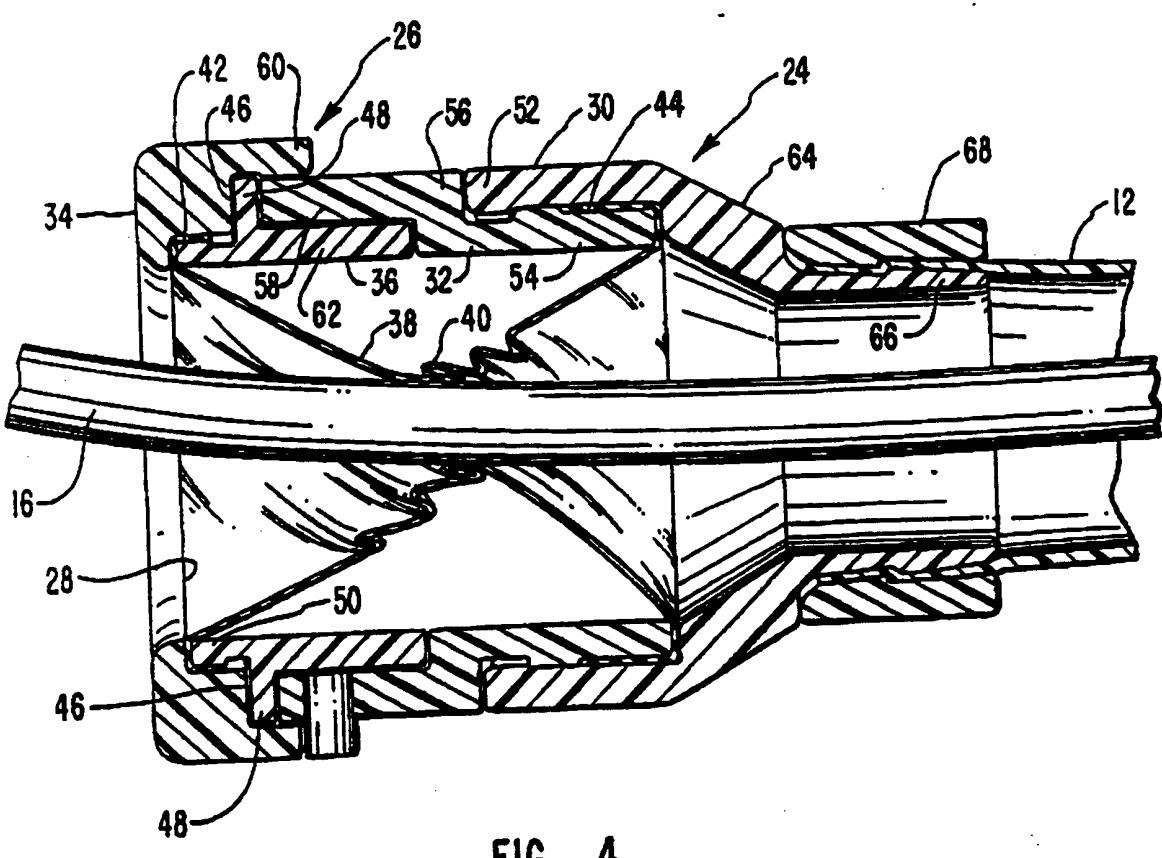
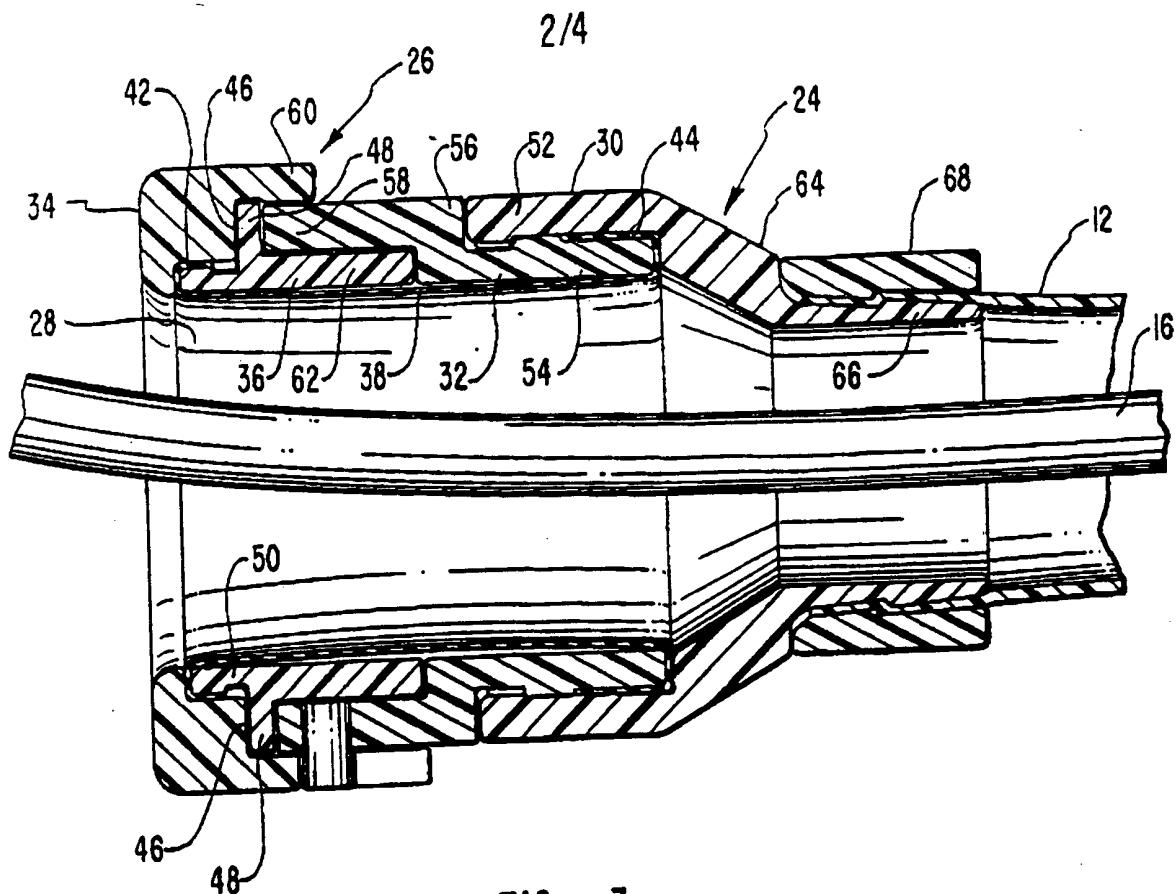


FIG. 2



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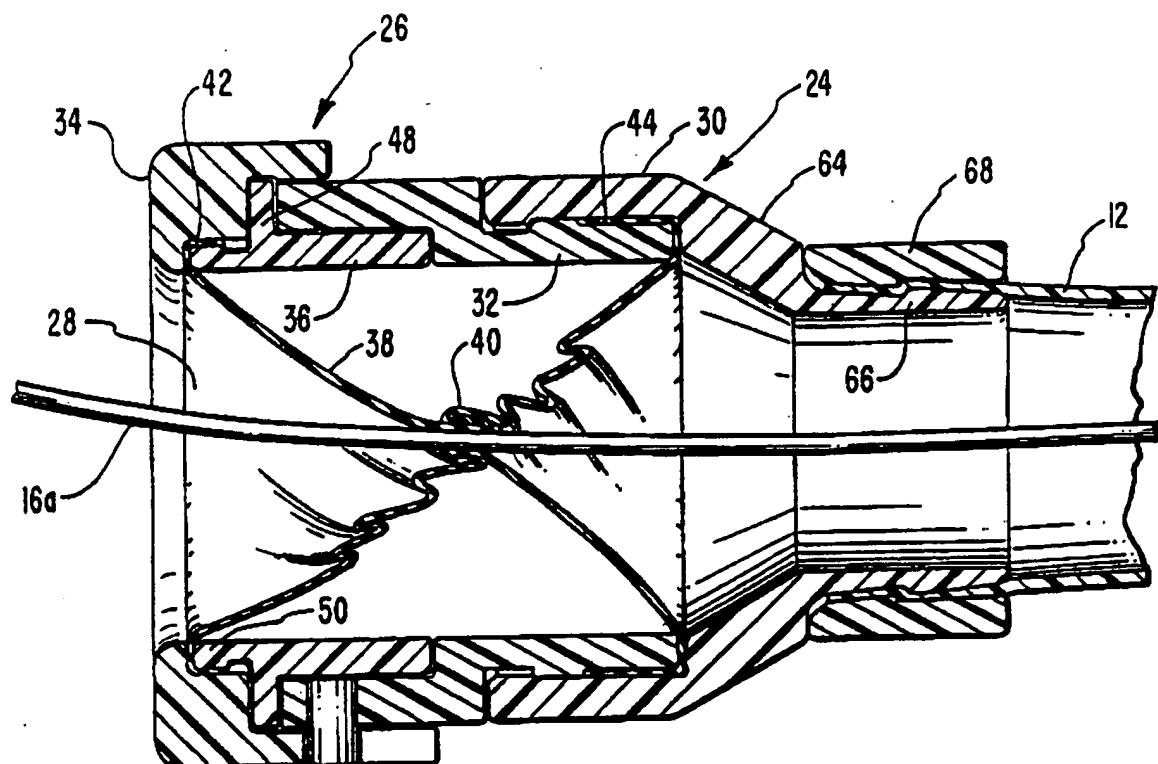


FIG. 5

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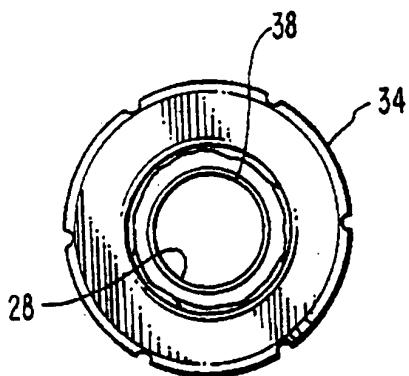


FIG. 6B

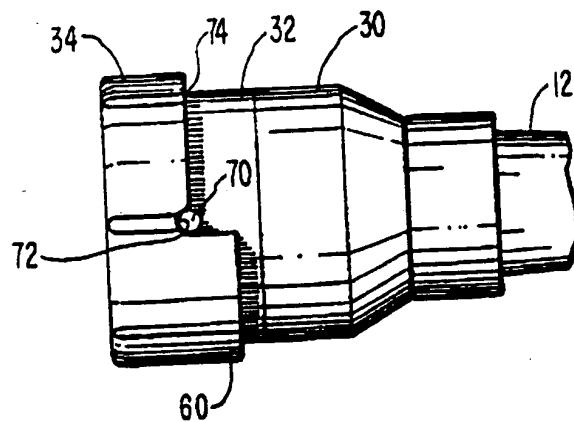


FIG. 6A

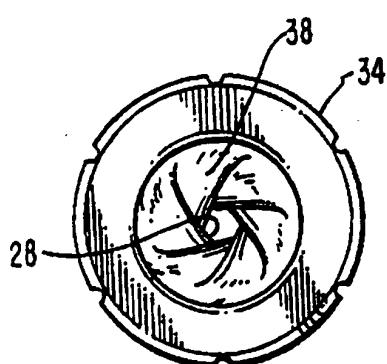


FIG. 6D

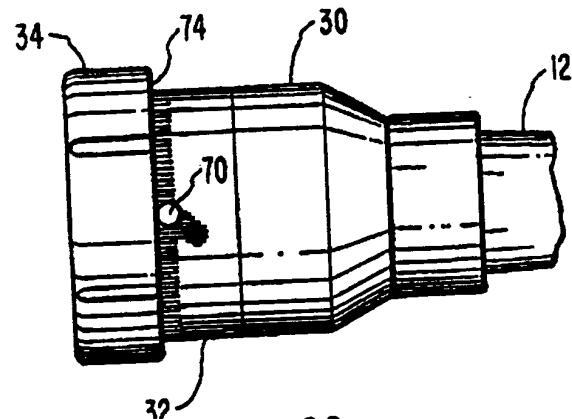


FIG. 6C

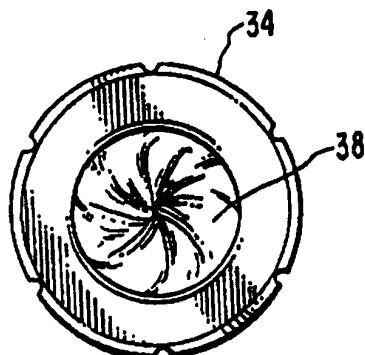


FIG. 6F

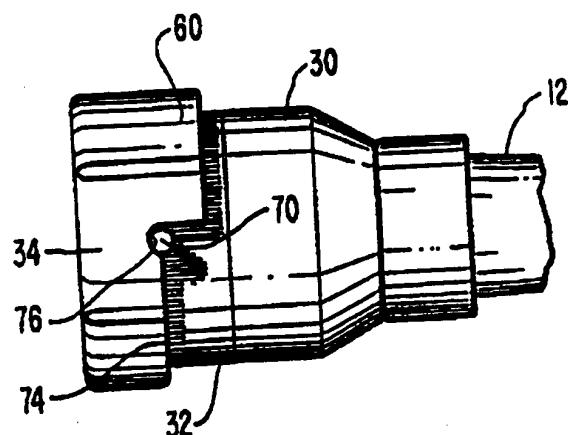


FIG. 6E

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/09699

I. CLASSIFICATION & SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 5/00 U.S. CL: 604/248

II. FIELDS SEARCHED

Minimum Documentation Searched¹

Classification System	Classification Symbols
U. S.	604/248, 256, 167, 246, 169, 164, 32, 237, 236, 264
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ²	

III. DOCUMENTS CONSIDERED TO BE RELEVANT³

Category ⁴	Citation of Document, ⁵ with indication, where appropriate, of the relevant passages ⁶	Relevant to Claim No. ⁷
X	US, A, 4,540,411 (BODICKY) 10 SEPTEMBER 1985	1-5, 8, 12, 19
Y	See the entire document.	22-24 6, 7, 9-11, 13-18, 20, 21
Y	US, A, 3,185,179 (HARAUTUNIAN) 25 MAY 1965 See Figures 4 and 5.	2-7, 9-18, 20-24
X	US, A, 4,580,573 (QUINN) 08 APRIL 1986	1, 8, 19
Y	See entire document.	2-7, 9-18, 20-24
A	US, A, 4,314,555 (SAGAE) 09 FEBRUARY 1982 See entire document.	1-24
A	US, A, 4,978,341 (NIEDERHAUSER) 18 DECEMBER 1990 See entire document.	1-24
A	US, A, 2,844,351 (SMITH) 22 JULY 1958 See entire document.	1-24

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

28 FEBRUARY 1992

International Searching Authority
ISA/US

Date of Mailing of this International Search Report

20 MARCH 1992

Signature of Authorized Officer

JEFFREY A. SMITH

